



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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TO: Staff, Office for Protection from Research Risks

FROM: Michele Russell-Einhorn, J.D.
Director of Regulatory Affairs

SUBJECT: Guidance on HHS Funded Research Involving Human Fetal Tissue

This memorandum addresses frequently asked questions regarding HHS sponsorship of research involving fetal tissue. Appropriate statutory and regulatory citations have been included.

A. STATUTORY AND REGULATORY REFERENCES

45 CFR 46.103 (Protection of Human Subjects)
45 CFR 46.210 (Additional DHHS Protections Pertaining to Research,
Development, and Related Activities Involving Fetuses,
Pregnant Women, and Human In vitro Fertilization)
Section 111, Public Law 103-43 (Research on Transplantation of Fetal Tissue)
Section 511, Public Law 105-27 (Fiscal Year 1999)

B. FREQUENTLY ASKED QUESTIONS

1. *Can HHS fund basic research involving human fetal tissue cells?*

Yes. If the research is funded by the Department of Health and Human Services (HHS), it must comply with any applicable state or local laws. Other than that, there

are no special provisions relating to basic research using human fetal tissue cells. See 45 CFR 46.210. Research involving transplantation of human fetal tissue is subject to special rules. See #3 below.

2. Does an IRB have to review research involving fetal tissue cells?

A researcher who receives funds from HHS should have an IRB review the research since 45 CFR 46.103(a) places responsibility on the institution to make sure that research conducted by the institution is in compliance with all provisions in the regulations. This would include 45 CFR 46.210 which requires that any research involving “the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws ...” Thus, the substantive requirement for HHS supported research involving fetal tissue cells is compliance with any applicable State or local laws.

This provision is contained in Subpart B of the HHS regulations.

A researcher who does not receive funds from HHS is not required to obtain IRB review of research involving fetal tissue cells, unless the institution has a Multiple Project Assurance (MPA) with OPRR which may require IRB review of all research regardless of funding source. In that case, the foregoing applies, and the IRB must assure compliance with any applicable State or local laws.

3. What are the special rules involving the transplantation of human fetal tissue cells?

Any research funded by HHS involving the transplantation of human fetal tissue cells is subject to the provisions of Section 111 of Public Law 103-43. This law contains the following eight requirements: (1) informed consent of the donor; (2) attending physician statement; (3) principal investigator statement; (4) informed consent of the recipient; (5) availability of statements for audit; (6) compliance with state law; (7) HHS annual report; and (8) tissue purchase and donation restrictions. This statutory provision contains numerous requirements within each of the eight categories summarized above and should be carefully reviewed when conducting research involving the transplantation of human fetal tissue cells.

4. How does the prohibition on research involving embryos contained in the HHS appropriations bill intersect with the rules regarding research on fetal tissue cells?

The rules regarding research on human embryos are as follows:

* HHS funds cannot support creating human embryos for research purposes.

(Public Law 105-277, Section 511 (Fiscal Year 1999))

* HHS funds cannot support research on embryos or fertilized human eggs that were originally created for treatment of infertility.

* HHS funds cannot support research in which human embryos are destroyed, discarded or knowingly subject to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(Public Law 105-277. Section 511 (Fiscal Year 1999))

HHS can fund research involving fetal tissue cells that were derived from human embryos that were created with private funds for research purposes, so long as the fetal tissue cells cannot be considered an organism. Researchers should also keep in mind the statutory prohibition on the use of HHS funds for cloning purposes. See January 15, 1999 Memorandum from HHS General Counsel Harriet S. Rabb to Harold Varmus, M.D., Director, NIH, *Federal Funding for Research Involving Human Pluripotent Stem Cells*.

5. Is research on improving abortion techniques allowed?

On December 16, 1986, the NIH Legal Advisor issued an opinion stating that HHS research funds could be used to support research on procedures to terminate ectopic pregnancies in human subjects. The research would have to meet the requirements set forth in Subpart B, 45 CFR 46.201 et. seq.

C. RULES RELATING TO RESEARCH INVOLVING A FETUS

1. Is research on a nonviable fetus allowed? Is research on a viable fetus allowed? What are the rules?

All HHS-supported research involving a fetus, whether viable or nonviable, must comply with Subpart B of 45 CFR Part 46 and Section 498(a) of Public Law 99-158. These legal authorities require certain determinations to be made before research on a fetus ex utero may go forward.

OPRR/MRE/July 12, 1999